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Filing Date: January 28, 2000

Applicants have amended claims 1-3 to recite with more particularity that which Applicants regard as their invention. Support for the amendments can be found within the claims as filed and throughout the specification. No new matter is being introduced with these amendments, and entry thereof is respectfully requested.

Prior to the present office action, Claims 1-18 were subject to a restriction requirement wherein Claims 1-11 were designated Group I, Claim 12 is designated Group II, Claims 13-15 are designated Group III, Claims 16-18 are designated Group IV, and Claim 16 is designated Group V. Applicants hereby confirm the election without traverse of Group I, Claims 1-11, drawn to a composition comprising a shrimp or prawn androgenic polypeptide, a method of producing neomale shrimp or prawn using the same, and a population of shrimp or prawns produced by the same method, classified in class 424, subclass 198.1. Applicants have canceled all claims falling within the unelected groups, Claims 12-18.

Thus, after entry of this amendment, Claims 1-11 are presented for further examination. A copy of the currently pending claims, after entry of the present amendment, is attached hereto for the Examiner's convenience.

A. The Invention

The present invention is directed toward an isolated androgenic peptide from shrimp or prawns, and its use in producing sexually reproductive neomale shrimp or prawns. This invention is further directed to the use of such sexually reproductive neomales in the production of shrimp or prawn populations having skewed ratios of females to males.

B. Rejections Under 35 U.S.C. § 101

Claims 10-11 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

Claim 10 recites a population of shrimp or prawn having a skewed percentage of females to males, the population being made according to the method of Claim 6. Claim 6 requires breeding sexually reproductive neomale shrimp or prawn not containing transplanted androgenic

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tissue to produce the population recited by Claim 10, independent Claim 11 is for a population of shrimp or prawns with a skewed percentage of females to males greater than about 90%.

The Examiner argues that Claims 10 and 11 read on a product of nature, and are therefore unpatentable subject matter. More specifically the Examiner argues that Claims 10 and 11 are interpreted as covering a population of normal shrimp or prawns. Applicants respectfully disagree.

Shrimp or prawn in nature do not naturally produce a population having a skewed percentage of females to males such as would be obtained in Claim 10 or covered by Claim 1. Thus, for this reason alone Claims 10 and 11 do not cover a natural population of shrimp or prawn. Moreover, the shrimp or prawn population recited by Claim 10 must be produced by breeding a sexually reproductive neomale shrimp or prawn not containing transplanted androgenic tissue with a female of the same species. Sexually reproductive neomale shrimp or prawn do not exist in nature. Therefore, for this additional reason the population of shrimp or prawn recited by Claim 10 does not exist in nature, and the claims do not cover a normal population of shrimp or prawn.

C. Rejections Under 35 U.S.C. § 103(a)

Claims 1-9 stand rejected under 35 U.S.C. § 103(a) as being obvious in light of Malecha *et al.*, in view of Okuno *et al.*; and Nagamine *et al.*

When rejecting claims under 35 U.S.C. § 103, the Examiner bears the burden of establishing a *prima facie* case of obviousness. *See, e.g., In re Bell*, 26 USPQ2d 1529 (Fed. Cir. 1993); M.P.E.P. § 2142. To establish a *prima facie* case, three basic criteria must be met. First, the prior art reference, or references when combined, must teach or suggest each and every limitation of the rejected claims. *See, e.g., M.P.E.P. § 706.02(j)*. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the teachings of the reference in the manner suggested by the Examiner. *See, e.g., In re Grabiak*, 226 USPQ 870 (Fed. Cir. 1985). Finally, the skilled artisan, in light of the teachings of the prior art, must have a reasonable

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expectation that the modification or combination suggested by the Examiner would be successful. *See, e.g., In re Dow*, 5 USPQ2d 1529, 1531-32 (Fed. Cir. 1988). The teaching or suggestion to make the claimed invention, as well as the reasonable expectation of success, must come from the prior art, not Applicant's disclosure. *In re Vaack*, 20 USPQ2d 1438 (Fed. Cir. 1991); M.P.E.P. § 706.02(j). If any one of these criteria is not met, *prima facie* obviousness is not established.

1. References Do Not Teach Or Suggest Each Element Of The Claimed Invention

Claims 1-9 stand rejected under 35 U.S.C. § 103(a) as being obvious over Malecha *et al.* in view of Okuna *et al.* and Nagamine *et al.*

Claim 1 requires, *inter alia*, an isolated shrimp or prawn androgenic polypeptide capable of producing a sexually reproductive neomale shrimp or prawn. Claim 2 requires a sexually reproductive neomale shrimp or prawn which do not contain transplanted androgenic gland tissue. Claim 3 requires, *inter alia*, treating shrimp or prawn with a composition comprising an androgenic peptide to produce a sexually reproductive neomale shrimp or prawn. Claim 6 requires, *inter alia*, breeding a sexually reproductive neomale shrimp or prawn not containing transplanted androgenic gland tissue to produce a population of prawn or shrimp having skewed percentages of females to males.

The Examiner admits that Malecha *et al.* do not teach producing a neomale by treating a female shrimp with a composition comprising an androgenic polypeptide, as recited in the claimed invention. The Examiner argues that this deficiency is made up by the teachings of Okuna *et al.* in combination with the teachings of Nagamine *et al.* More specifically, the Examiner argues that the teaching by Okuna *et al.*—AGH masculinizes *Armadillidium vulgare*—, in combination with the suggestion by Nagamine *et al.*—the androgenic glands (AG) of *isopods*, *decapods*, *amphipods* may function similarly—render it obvious to treat a female shrimp or prawn with an androgenic polypeptide to produce a sexually reproductive neomale shrimp or prawn. Applicants respectfully disagree.

Malecha *et al.* teach a method of producing sexually reproductive neomale prawn by implanting the androgenic gland of a male prawn into a female prawn. Further, Malecha *et al.*

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teach a method of crossbreeding these neomale prawns with normal females to produce a population having a skewed percentage of females to males. Significantly, Malecha *et al.* do not teach or suggest an isolated shrimp or prawn androgenic polypeptide capable of producing a sexually reproductive neomale, nor a method of using the polypeptide to produce a sexually reproductive neomale.

Okuna *et al.* do not make up for the deficiencies of Malecha *et al.* Okuna *et al.* teach the purification of androgenic hormone (AGH) from isolated androgenic glands of *A. vulgare*, a terrestrial isopod only distantly related to the marine animals of the present invention. Further, Okuna *et al.* teach that injecting 38pg of AGH into female *A. vulgare* results in "masculinization." "Masculinization" is defined by Okuno *et al.* as being limited to elongation of the endopodites of the first pair of abdominal legs. Masculinization, as defined by Okuno *et al.*, is significantly different from formation of a sexually reproductive neomale, as recited by the claims. Significantly, Okuna *et al.* never produce a sexually reproductive neomale *A. vulgare*, let alone a sexually reproductive neomale shrimp or prawn.

Nagamine *et al.*, alone or in combination with Okuna *et al.*, also do not make up for the deficiencies of Malecha *et al.* Nagamine *et al.* teach transplanting *Macrobrachium rosenbergii* AG into females of the same species. Significantly, the transplantation taught by Nagamine *et al.* resulted only in masculinization and never resulted in a sexually reproductive neomale.

Thus, the references, taken alone or in any combination, do not teach or suggest the an isolated shrimp or prawn androgenic polypeptide capable of producing a *sexually reproductive* neomale, or the production of a *sexually reproductive* neomale shrimp or prawn using the androgenic polypeptide, as required by the claimed invention. Therefore, the references, taken alone or in any combination, do not teach or suggest each and every element of Claims 1-9. For this reason alone the Examiner has failed to make out a *prima facie* case of obviousness against Claims 1-9.

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2. References Do Not Provide A Reasonable Expectation Of Success

Moreover, the references, taken alone or in any combination, do not provide the skilled artisan with any reasonable expectation of successfully producing a sexually reproductive neomale shrimp or prawn from an isolated androgenic polypeptide. As discussed, Okuna *et al.* merely masculinized *A. vulgare*, by injecting *A. Vulgare* AGH into a female of the same species. Further, *A. vulgare* is a terrestrial isopod only distantly related to the marine animals of the present invention. The mere suggestion by Nagamine *et al.* that androgenic glands from *isopods*, *decapods*, *amphipods* may perform similar functions does not provide any reasonable expectation that shrimp or prawn androgenic hormone would successfully produce a sexually reproductive neomale shrimp or prawn. This is especially true when Okuno *et al.* do not even succeed in producing a sexually reproductive neomale *A. vulgare*. At best Malecha *et al.*, in view of Okuno *et al.* and Nagamine *et al.* piques the skilled artisan's curiosity for further experimentation. However, it has been "consistently held that 'obvious to try' is not to be equated with obviousness" *The Gillette Co. v. S.C. Johnson & Son Inc.*, 16 USPQ2d 1923, 1928 (Fed. Cir. 1990):

None of the references, taken alone or in any combination, provide an adequate disclosure to successfully isolate shrimp or prawn androgenic polypeptide capable of producing a sexually reproductive neomale, or to successfully produce a sexually reproductive neomale shrimp or prawn using the polypeptide. For this additional reason the Examiner has failed to establish a *prima facie* case of obviousness against Claim 1-9.

3. Conclusion

Applicants respectfully submit that the Examiner has failed to make out a *prima facie* case of obviousness against Claims 1-9. More specifically, the references, taken alone or in any combination, do not teach or suggest each and every element of the claimed invention. Moreover, none of the references, taken alone or in any combination, provide a reasonable expectation of successfully producing a sexually reproductive neomale shrimp or prawn by using an androgenic polypeptide. Accordingly, Applicants respectfully request the Examiner to withdraw the rejection

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of Claims 1-9 under 35 U.S.C. § 103(a) as being obvious over Malecha *et al.* in view of Okuno *et al.* and Nagamine *et al.*

CONCLUSION


Applicant respectfully submits that Claims 1-11 satisfy all of the requirements for patentability and are in condition for allowance. Early passage to issuance of these claims is therefore kindly solicited.

If the Examiner has further unresolved issues after considering this amendment, the Examiner is respectfully requested to phone the undersigned attorney.

Respectfully submitted,

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Appendix of Pending Claims

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1. (Amended) A composition comprising an isolated shrimp or prawn androgenic polypeptide capable of producing a sexually reproductive neomale shrimp or prawn.
2. (Amended) A sexually reproductive neomale shrimp or prawn which does not contain transplanted androgenic gland tissue.
3. (Amended) A method of producing a sexually reproductive neomale shrimp or prawn comprising:
treating a shrimp or prawn with a composition comprising an androgenic peptide to produce a sexually reproductive neomale shrimp or prawn.
4. The method of claim 3, wherein said treating comprises injecting.
5. The method of claim 3, wherein said treating comprises contacting.
6. A method of producing a population of shrimp or prawns having a skewed percentage of females to males, comprising:
breeding a neomale shrimp or prawn which does not contain transplanted androgenic tissue with a corresponding female shrimp or prawn, whereby a population of shrimp or prawns having a skewed ratio of males to females is produced.
7. The method of claim 6, wherein said percentage of females is greater than about 80%.
8. The method of claim 6, wherein said percentage of females is greater than about 90%.
9. The method of claim 6, wherein said percentage of females is 100%.

Appendix of Pending Claims

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10. A population of shrimp or prawns having a skewed percentage of females to males made according to the method of claim 6.
11. A population of shrimp or prawns having a skewed percentage of females to males of greater than about 90%.